UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF NEW YORK

ENZO BIOCHEM, INC. et al.,	)	
	)	
Plaintiffs,	)	
	)	
v.	)	03 CV 3816 (RJS)
	)	
MOLECULAR PROBES, INC.,	)	
	)	
Defendant,	)	
and	)	**ORAL ARGUMENT REQUESTED**
	)	
YALE UNIVERSITY,	)	
	)	
Nominal Defendant.	)	

MOLECULAR PROBES, INC.'S MEMORANDUM OF LAW IN SUPPORT OF ITS MOTION FOR PARTIAL SUMMARY JUDGMENT
ON ENZO'S INFRINGEMENT CLAIMS AGAINST MPI'S ULYSIS PRODUCTS

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I. PRELIMINARY STATEMENT

Enzo Biochem, Inc.'s and Enzo Life Sciences, Inc.'s (collectively, "Enzo") infringement claims against MPI's ULYSIS Nucleic Acid Labeling Kits should be dismissed on summary judgment based on Enzo's recent representations to the PTO that preclude infringement by those products. Although Enzo asserts that the ULYSIS products infringe claim 1 of U.S. Patent No. 5,241,060 (the "'060 patent")[1], in the pending reexamination of that patent Enzo expressly limited claim 1 such that it does not cover the ULYSIS products. To avoid prior art, Enzo represented that claim 1 of the '060 patent covers only freestanding mononucleotides that are labeled prior to incorporation into a nucleic acid molecule, and that claim 1 does not cover labeling of already-formed nucleic acid molecules such as oligo- or poly-nucleotides. MPI's ULYSIS products do not (indeed cannot) label free-standing mononucleotides. Rather, the ULYSIS kits label only already-formed oligo or poly-nucleotides (*i.e.,* nucleic acid molecules such as a DNA or RNA). Enzo's representations to the PTO directly contradict and fatally undermine its infringement contentions, which were based entirely on the ULYSIS kits' attachment of a label to a DNA, RNA or other already-formed nucleic acid molecule – precisely the subject matter that Enzo specifically disclaimed.

Enzo made clear and unmistakable disavowals to the PTO to avoid prior art in the reexamination. Those disavowals are part of the intrinsic record of the '060 patent, limit the patent's scope such that the ULYSIS products cannot infringe, and are binding on Enzo. Accordingly, MPI is entitled to summary judgment of no infringement by the ULYSIS products.[2]

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[1] Pursuant to the Court's Individual Practice Rule 2.B, Enzo's May 27, 2003 Complaint is attached as **Exhibit 1** to the Declaration of Eric M. Jaegers (the "Jaegers Decl."). All Exhibits are attached to the Jaegers Decl.

[2] [redacted]

II. STATEMENT OF FACTS[3]

A. The '060 Patent and the Relevant Technology.

Enzo accuses MPI's ULYSIS products of infringing only claim 1 of the '060 patent. **Exhibit 2** (filed as Exhibit 1 to the MacLean Decl. to Enzo's Opposition to Defendants' Joint Summary Judgment Motion (Dkt. No. 267-1 in related case No.02-cv-8448)). Claim 1 states:

> A nucleotide having the formula PM-SM-BASE-Sig wherein PM is a phosphate moiety, SM is a sugar moiety, BASE is a pyrimidine, purine or 7-deazapurine moiety, PM being attached at the 3' or the 5' position of SM when the nucleotide is a deoxyribonucleotide and at the 2', 3' or 5' position when the nucleotide is a ribonucleotide, BASE being attached to the 1' position of the SM from the N^1 position when BASE is a pyrimidine or the N^9 position when BASE is a purine or a 7-deazapurine, and Sig is covalently attached to BASE at a position other than the C^5 position when BASE is a pyrimidine, at a position other than the C^8 position when BASE is a purine and at a position other than the C^7 position when BASE is a 7-deazapurine and wherein Sig represents a detectable moiety.

Id. at **Exhibit 3** ('060 patent, Col. 31:14-28).

A "nucleotide" is a molecule composed of a sugar, a base, and a phosphate group. **Exhibit 4** at ¶¶17, 23 (declaration from Enzo expert Dr. Sinden) ("the term nucleo*tide* refers to the combination of a base, sugar and phosphate group."). Single nucleotides are the building blocks of nucleic acids such as DNA and RNA, which are larger molecules composed of multiple, joined single nucleotides. **Exhibits 4** (Sinden Decl. at ¶23) and **5** (Sept. 11-12 2006 Singer Depo., Vol. 2, at 385:2-3) [redacted]). Before being joined together to form a nucleic acid such as DNA or RNA, a nucleotide is called a mononucleotide or single nucleotide. **Exhibits 4** at ¶¶17, 23, 68 (Sinden Decl.) and **6** (Enzo's Response to PTO at 6-7 and at 22-23 (Rokita Decl., ¶¶3-5)). Once chemically incorporated into a nucleic acid molecule, the nucleotide building blocks are called "nucleotide residues." **Exhibit 6** (Enzo's Response at 7 and at 22 (Rokita Decl., ¶3) ("claim 1 is directed to mononucleotides (as opposed to single nucleotide residues within oligo- or polynucleotides.")).

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[3] MPI adopts and incorporates by reference its contemporaneously-filed Local Rule 56.1 Statement of Material Facts filed with this Memorandum of Law.

Based on the number of nucleotide residues in a DNA or RNA molecule, it may be referred to as an "oligonucleotide" (containing a *few* nucleotides) or "polynucleotide" (containing *many* nucleotides). **Exhibits 4** (Sinden Decl. at ¶24); **5** (Sept. 11-12, 2006 Singer Depo., Vol. 2, at 399:5-10, 20-21) [redacted]. By definition, a nucleic acid (*i.e*. DNA, RNA or another oligo- or polynucleotide) is not a mononucleotide. **Exhibit 5** (Sept. 11-12 2006 Singer Depo., Vol. 2, at 385:1-2 and 399:14-15) [redacted]). These scientific facts are not in dispute.

B. Enzo's Representations to the PTO in Reexamination Clearly and Unmistakably Disavowed the Scope of the '060 Patent.

On June 15, 2012, MPI requested *ex parte* reexamination of claims 1-3 of the '060 patent. **Exhibit 7** (PTO's Office Action at 1, 3). On July 28, 2012, the PTO granted MPI's request, and on February 6, 2013, rejected claims 1-3 as invalid over the prior art. *Id.*

On May 6, 2013, Enzo responded to the PTO's rejections, defining the scope of claim 1 as follows:

> More particularly, the patent relates to hybridization probes that are formed by *first* labeling a mononucleotide with a detectable moiety (termed "Sig" in the patent), and *subsequently* incorporating the labeled mononucleotide into an oligo- or polynucleotide probe using a polymerase (*e.g*. a terminal transferase). (*See* col. 2, lines 57-62; col. 25, lines 41-48).
>
> Claim 1 of the '060 Patent recites "[a] nucleotide" defined by the formula "PM-SM-BASE-Sig" and claims 2 and 3 each recite oligo- and polynucleotides "comprising at least one nucleotide in accordance with claim 1." The '060 Patent and its prosecution history make clear that claim 1 is directed to mononucleotides (as opposed to single nucleotide residues within oligo- or polynucleotides) and claims 2 and 3 are DNA or RNA probes into which a mononucleotide of claim 1 has been incorporated. (*See* Rokita Decl. ¶3). That means that the labeled mononucleotides of claim 1 must exist independently prior to their incorporation into the oligo- or polynucleotide probes of claims 2 and 3. (*Id.*). * * *
>
> By distinguishing between "nucleotides" and "polynucleotides" and identifying the species of claim 1 as a "nucleotide" (rather than a polynucleotide), claim 1 is clearly intended to cover only labeled mononucleotides. (*Id.*). This distinction is also found in the claims themselves: by separately reciting an "oligo- or polynucleotide comprising [a claim 1 nucleotide]" in claims 2 and 3, the

> "nucleotide" of claim 1 by implication must be a mononucleotide. (*Id.*). . . . Dr. Rokita further explains that the focus of the '060 Patent is to label mononucleotides and then to attach the labeled mononucleotides to a piece of DNA or RNA using polymerases (Rokita Decl. ¶5)[.].

Exhibit 6 (Enzo's Response at 6-7 (emphasis in original)). Rather than use its litigation expert, Dr. Sinden, to support its statements to the PTO, Enzo relied on a declaration from a new expert (Dr. Rokita) who is not engaged in this litigation. *Id.* Through the Rokita declaration, Enzo made the following additional representations to the PTO:

> This conclusion is also supported by the claims themselves which echo this distinction by separately reciting oligo- and polynucleotides in claims 2 and 3 as different from the 'nucleotide' of claim 1.
>
> Moreover, it is clear that the focus of the '060 Patent is to label mononucleotides and then to attach the labeled mononucleotides to a piece of DNA or RNA.

Exhibit 6 (Enzo's Response at 22 (Rokita Decl., ¶¶4-5)). Enzo's Response represents that claim 1 of the '060 patent covers labeled mononucleotides only and that claim 1 cannot cover products like ULYSIS that put labels onto already-formed nucleic acids such as DNA or RNA molecules (*i.e.* oligo- or polynucleotides).

C. Enzo's Infringement Contentions Are Contradicted and Fatally Undermined by Its Representations to the PTO.

Enzo's infringement contentions assert that MPI's ULYSIS products infringe because they are used to label already-formed nucleic acids: [redacted]

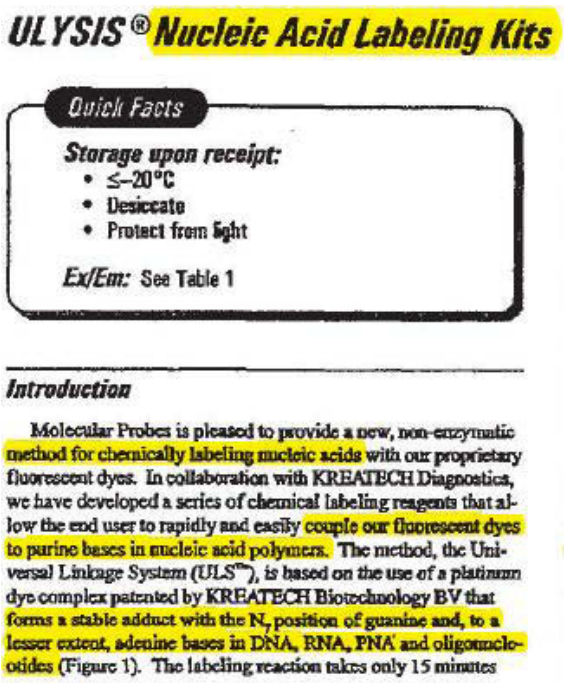
[redacted] **Exhibit 8**[4] at 1 (Enzo's infringement contentions) (emphasis added). Enzo did not assert that ULYSIS labels an individual, free-standing **nucleotide.** In contrast, Enzo's representations to the PTO assert that claim 1 covers only free-standing nucleotides, separate from and before being incorporated into a nucleic acid molecule: "By distinguishing between 'nucleotides' and 'polynucleotides' and identifying the species of claim 1 as a 'nucleotide,'

[4] MPI's **Exhibit 8** is a copy of Enzo's infringement contentions relating to the ULYSIS products. Enzo previously filed these contentions as an exhibit to its December 13, 2011 Opposition to the defendants' Joint Motion for Summary Judgment on Enzo's Patent Claims. *See* Exhibit 14-H to Dr. Sinden's expert declaration (*filed under seal* as Dkt. No. 269-77 in related Cause No.02-cv-8448).

(rather than a polynucleotide), claim 1 is clearly intended to cover only labeled mononucleotides." *Id.* at **Exhibit 6** (Enzo's Response at 7 (emphasis in original)). Accordingly, Enzo's sole theory of infringement is that the ULYSIS products work in a manner that Enzo itself concedes does not infringe the '060 patent. *Id.*

D. MPI's ULYSIS Products Do Not Label Mononucleotides.

MPI's ULYSIS products[5] are "Nucleic Acid Labeling Kits," and the Product Information Sheet describes precisely what they do: provide researchers a "non-enzymatic method for chemically labeling nucleic acids" with MPI's proprietary dyes. **Exhibit 9** (ULYSIS Product Information Sheet) (emphasis added). The information sheet never uses the word "nucleotide," instead referring to nucleic acid(s) (over 10 times), DNA (over 25 times), RNA (6 times), and oligonucleotide (once). *Id.* Below is an excerpt from the ULYSIS Product Information Sheet detailing the products' use with nucleic acids polymers:



ULYSIS® Nucleic Acid Labeling Kits

Quick Facts

Storage upon receipt:
- ≤–20°C
- Desiccate
- Protect from light

Ex/Em: See Table 1

Introduction

Molecular Probes is pleased to provide a new, non-enzymatic method for chemically labeling nucleic acids with our proprietary fluorescent dyes. In collaboration with KREATECH Diagnostics, we have developed a series of chemical labeling reagents that allow the end user to rapidly and easily couple our fluorescent dyes to purine bases in nucleic acid polymers. The method, the Universal Linkage System (ULS™), is based on the use of a platinum dye complex patented by KREATECH Biotechnology BV that forms a stable adduct with the N$_7$ position of guanine and, to a lesser extent, adenine bases in DNA, RNA, PNA and oligonucleotides (Figure 1). The labeling reaction takes only 15 minutes

Id. (*see also* highlighted portions on p. 2 and p. 3).

MPI's ULYSIS products do not label mononucleotides:

[5] For a list of the ten (10) accused ULYSIS products, MPI refers the Court to **Exhibit 2**.

Q: [redacted]

A: [redacted]

***

Q: [redacted]

A: [redacted].

Exhibit 5 (Sept. 11-12, 2006 Singer Depo., Vol. 2, at 384:20–385:2; 391:19–392:1) (emphasis added).[6]

III. ARGUMENT: SUMMARY JUDGMENT IS PROPER ON ENZO'S INFRINGEMENT CLAIMS AGAINST MPI'S ULYSIS PRODUCTS

A. Legal Standards.

Determining infringement is a two-step process in which the court construes the claims as a matter of law and then compares the properly construed claims to the accused products. *Innova/Pure Water, Inc. v. Safari Water Filtration Syst., Inc.*, 381 F.3d 1111, 1115 (Fed. Cir. 2004). When there are no genuine disputes of material fact concerning the accused products, the infringement analysis collapses into claim construction and the matter is amenable to summary judgment. *Desper Prods., Inc. v. QSound Labs, Inc.*, 157 F.3d 1325, 1332-33 (Fed. Cir. 1998). Where claim terms are not in dispute, construction is not necessary. *Hakim v. Cannon Avent Group, PLC*, 479 F.3d 1313, 1318-19 (Fed. Cir. 2007); *Laboratories Perouse, S.A.S. v. W.L. Gore & Assoc., Inc.*, 528 F. Supp. 2d 362, 393 (S.D.N.Y. 2007) (refusing to construe terms not in dispute). Because Enzo bears the burden of proving infringement, MPI need only state that Enzo has no evidence of infringement and leave Enzo to its proof. *See Exigent Tech., Inc. v. Atrana*

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[6] Enzo has questioned MPI's witnesses about the ULYSIS products many times, and the responses have always been the same: the products label only nucleic acids, not mononucleotides. *See* **Exhibits 5** (Sept. 11-12, 2006 Singer Depo., Vol. 2, at 384:14–385:17; 388:1-5; and 391:19–392:1), **10** (Feb. 25, 2003 Gee Depo. at 82:11-21) ([redacted]), **11** (Sept. 12, 2006 Hendrickson Depo. at 32:9-14 [redacted]) and 33:18–34:2 [redacted]), and **12** (April 9, 2013 Singer Depo. at 32:20-23) [redacted] and 36:13-19, 38:4-6 ([redacted]

Solutions, Inc., 442 F.3d 1301, 1309 (Fed. Cir. 2006) (granting summary judgment of no infringement).

To prevail on an infringement claim, the patentee must establish that each limitation of a claim is met by the accused product, either literally or under the doctrine of equivalents. *Mas-Hamilton Group v. LaGard, Inc.*, 156 F.3d 1206, 1211 (Fed. Cir. 1998); *Sage Prods., Inc. v. Devon Indus., Inc.*, 126 F.3d 1420, 1423 (Fed. Cir. 1997). Literal infringement cannot be found where the patentee disclaims or disavows claim scope before the PTO in a manner that excludes the accused product. *See, e.g., Rheox, Inc. v. Entact, Inc.,* 276 F.3d 1319, 1325 (Fed. Cir. 2002) (affirming summary judgment of non-infringement based on limiting representations to the PTO, explaining "[e]xplicit arguments made during prosecution to overcome prior art can lead to narrow claim interpretations because '[t]he public has a right to rely on such definitive statements made during prosecution.'") (quoting *Digital Biometrics, Inc. v. Identix, Inc.,* 149 F.3d 1335, 1347 (Fed. Cir. 1998)); *Regents of the Univ. of Minn.*, Case No. 2012-1167, 2013 U.S. App. LEXIS 11077, at *30 (Fed. Cir. June 3, 2012) ("When an applicant tells the PTO that a prior art reference lies outside the scope of his claim, he is bound by that argument").

Infringement under the doctrine of equivalents can occur where a claim limitation is not literally found in an accused product but the relevant aspect of the accused product "performs substantially the same function in substantially the same way with substantially the same result as each claim limitation of the patented product" or otherwise is insubstantially different from the claim limitation. *Brilliant Instruments, Inc. v. GuideTech, LLC*, 707 F.3d 1342, 1346-47 (Fed. Cir. 2013). However, prosecution history estoppel ("PHE") limits the doctrine of equivalents by barring a patentee from asserting as "equivalent" any subject matter that it surrendered before the PTO. *Warner-Jenkinson Co., Inc. v. Hilton Davis Chem. Co.*, 520 U.S. 17, 39 n.8 (1997); *Duramed Pharm., Inc. v. Paddock Lab., Inc.*, 644 F.3d 1376, 1380 (Fed. Cir. 2011) (citing *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.*, 535 U.S. 722, 734, 122 S. Ct. 1831, 152 L. Ed. 2d 944 (2002) ("*Festo VIII*")). Application of PHE is a matter of law, *Pall Corp. v. Hemasure, Inc.,* 181 F.3d 1305, 1311 (Fed. Cir. 1999), and the "scope of estoppel, *i.e.,*

what subject matter has been surrendered during prosecution by the patentee, is to be viewed from the vantage point of a reasonable competitor of the patentee." *Sextant Avionique, S.A. v. Analog Devices, Inc.,* 172 F.3d 817, 826-27 (Fed. Cir. 1999). PHE applies where a patentee limits the scope of its claims by distinguishing its invention from the prior art. *Pioneer Magnetics, Inc. v. Micro Linear Corp*., 330 F.3d 1352, 1357 (Fed. Cir. 2003) (amending claim to avoid prior art is "the classic basis for the application of prosecution history estoppel." (citing *Warner-Jenkinson*, 520 U.S. at 30-31)). Summary judgment of no literal infringement and no infringement under the doctrine of equivalents should be granted where there is no genuine dispute that the accused product lacks at least one claim limitation. *Spectrum Int'l, Inc. v. Sterilite Corp.*, 164 F.3d 1372, 1380 (Fed. Cir. 1998).

B. Enzo's Representations to the PTO are a Clear and Unmistakable Disavowal of the Scope of the '060 Patent.

Enzo's reexamination representations were made specifically to avoid the cited prior art and accordingly are a clear and unmistakable disavowal limiting the scope of claim 1 for purposes of infringement. *See e.g., Computer Docking Station Corp. v. Dell, Inc*., 519 F.3d 1366, 1374-75 (Fed. Cir. 2008) (affirming summary judgment of non-infringement based on plaintiff's statements to PTO during patent prosecution); *Dey, Inc. v. Sepracor, Inc*., 847 F. Supp. 2d 541, 559 (S.D.N.Y. 2012), *rev'd on other grounds*, 2013 U.S. App. LEXIS 10010 (May 20, 2013) (granting summary judgment regarding intervening rights and stating that "explicit disavowal of the scope of a claim, even where the claim language is silent, can operate to limit the claim"). District courts may properly rely on documents submitted to the PTO during reexamination as those documents are part of the intrinsic record. *Biosig Instruments, Inc. v. Nautilus, Inc.*, 715 F.3d 891, 899-901 (Fed. Cir. 2013); *Proctor & Gamble Co. v. Kraft Foods Global, Inc.*, 549 F.3d 842, 848 (Fed. Cir. 2008).

To avoid a prior art reference (the Draper reference) that Enzo characterizes as labeling only nucleic acids (*i.e.*, oligo- or poly-nucleotides), Enzo represented that the '060 patent requires that "mononucleotides" are labeled "*first*" and then "*subsequently* incorporat[ed]" into

an oligo- or polynucleotide. **Exhibit 6** (Enzo's Response at 6) (emphasis in original). Enzo repeatedly emphasized this limitation of claim 1::

> [T]he labeled mononucleotides of claim 1 must exist independently prior to their incorporation into the oligo- or polynucleotide.
>
> By distinguishing between 'nucleotides' and 'polynucleotides' and identifying the species of claim 1 as a 'nucleotide,' (rather than a polynucleotide), claim 1 is clearly intended to cover only labeled mononucleotides.
>
> ***
>
> [t]his conclusion is also supported by the claims themselves which echo this distinction by separately reciting oligo- and polynucleotides in claims 2 and 3 as different from the 'nucleotide' of claim 1 . . .. Moreover, it is clear that the focus of the '060 Patent is to label mononucleotides and then to attach the labeled mononucleotides to a piece of DNA or RNA.

Id. at 7 (emphasis original), 23 (Rokita Decl., ¶¶4-5).

Enzo's formal disavowals before the PTO are now part of the '060 patent's official file history, and they bind Enzo as part of the inescapable intrinsic evidence in the PTO. *See Regents of the Univ. of Minn.*, 2013 U.S. App. LEXIS 11077, at *30 ("[w]hen an applicant tells the PTO that a prior art reference lies outside the scope of his claim, he is bound by that argument."); *Biosig*, 715 F.3d at 899-901. Because this is Enzo's own limitation on the scope of claim 1 of the '060 patent, it precludes any genuine issue of fact regarding whether the "nucleotide" of claim 1 is limited to stand-alone, labeled mononucleotides.[7]

C. Enzo's Infringement Claims Fail as a Matter of Law.

Enzo's attempt to distinguish the prior art has torpedoed its infringement theory as to MPI's ULYSIS products, under both a literal infringement theory and the doctrine of equivalents.

1. Enzo's literal infringement claims must fail.

There is no genuine issue of fact that MPI's ULYSIS products label only oligo- and polynucleotides: a mononucleotide is never involved. **Exhibits 9** (ULYSIS Product Information Sheet) and **5** (Sept. 11-12, 2006 Singer Depo., Vol. 2, at 384:20–385:2; 391:19–392:1). The ULYSIS products start with and label only a DNA or RNA – *i.e.,* a fully formed nucleic acid,

[7] Regardless of whether Enzo's interpretation of claim 1 is the correct one in the reexamination proceeding, the operative issue here is that Enzo has in fact made the statements.

such as an oligo- or polynucleotide. *Id.* The product information sheet describing the products, used at a deposition of an MPI witness, does not even use the word "nucleotide," instead referring to the labeling of nucleic acids, DNA, RNA, and oligonucleotides over 45 times. *Id.* As such, the ULYSIS products do not "*first* label[] a mononucleotide with a detectable moiety …, and *subsequently* incorporat[e] the labeled mononucleotide into an oligo- or polynucleotide" as argued by Enzo in the reexamination. **Exhibit 6** (Enzo's Response at 6-7); *see also* **Exhibits 5, 8-12**, and MPI's Rule 56.1 Statement at ¶20. The ULYSIS products also do not use or create mononucleotides that "exist independently prior to their incorporation into the oligo- or polynucleotide probes of claims 2 and 3", nor do they "label mononucleotides and then [] attach the labeled mononucleotides to a piece of DNA or RNA," as claim 1 was limited by Enzo before the PTO. **Exhibits 5-6, 8-12** and MPI's Rule 56.1 Statement at ¶¶21-22.

Nevertheless, Enzo has asserted in this case that the ULYSIS products infringe based on the very subject matter it has disclaimed in the reexamination: [redacted] **Exhibit 8** (Enzo's infringement contentions) (emphasis added). Because Enzo represented that prior art in which only an oligo- or poly-nucleotide is labeled is not within the scope of the claims, Enzo has specifically disclaimed infringement by products like ULYSIS that label only oligo- or poly-nucleotides. *Id.* Accordingly, Enzo's infringement theory is fundamentally and fatally undermined by its representations to the PTO in the reexamination[8] and cannot stand. Summary judgment of no literal infringement is therefore warranted.

[8] Enzo is inescapably bound by its statements to the PTO – it cannot disavow the scope of the '060 patent before the PTO and then reclaim that subject matter in this Court. *Computer Docking Station,* 519 F.3d at 1379 (party "cannot recapture scope disavowed during prosecution to prove infringement."), *Regents of the Univ. of Minn.,* 2013 U.S. App. LEXIS 11077 at *30 ("When an applicant tells the PTO that a prior art reference lies outside the scope of his claim, he is bound by that argument").

2. Enzo has waived any claim under the doctrine of equivalents.

Enzo's Complaint does not assert infringement by equivalents. **Exhibit 1**. Enzo has never submitted infringement contentions articulating an equivalents argument against the ULYSIS products. **Exhibit 8** represents the extent of Enzo's infringement contentions against the ULYSIS products after years of litigation. Missing from that document is any limitation-by-limitation application of either the function-way-result test or insubstantial differences test required to prove infringement by equivalents. *See Brilliant Instruments*, 707 F.3d at 1346-47.

Summary judgment is proper on a doctrine of equivalents claim where, like Enzo, a party waives the claim by failing to assert it in any meaningful way. *See, e.g., STMicroelectronics, Inc. v. Sandisk Corp*., 4:05-cv-44, 2006 U.S. Dist. LEXIS 42469, **23-24 (E.D. Tex. June 22, 2006) (granting summary judgment of no infringement where plaintiff neither pled nor presented evidence on equivalents and expert merely "devotes three lines in his report stating, in effect, that Tower and UMC processes infringe under the doctrine of equivalents."). Failure to amend infringement contentions "to add any of the required detail" is fatal to an equivalents claim and "bar[s] use of the doctrine." *Realtime Data, LLC v. Morgan Stanley*, 11-cv-6696, 2012 U.S. Dist. LEXIS 109954, **32-33 (S.D.N.Y. Aug. 2, 2012) (striking equivalents theory first disclosed in expert report because discovery responses initially included only "placeholder" for equivalents claim and later dropped it). Additionally, Federal Rule of Civil Procedure 37(c) bars the use of untimely expert opinions because it amounts to "sandbagging" adverse parties. *Lujan v. Cabana Mgmt., Inc.*, 284 F.R.D. 40, 77 (S.D.N.Y. 2012).

Here, Enzo has neither pled equivalents nor offered any limitation-by-limitation analysis of either the function-way-result test or insubstantial differences test. *See, e.g. Mirror Worlds, LLC v. Apple Inc.,* 692 F.3d 1351, 1357 (Fed. Cir. 2012) ("Regardless [of] how the equivalence test is articulated, 'the doctrine of equivalents must be applied to individual limitations of the claim, not to the invention as a whole.'") (quoting *Warner-Jenkinson Co. v. Hilton Davis Chem. Co.,* 520 U.S. 17, 29 (1997)). Enzo likewise has offered no evidence at all, let alone "particularized testimony," regarding an equivalents claim. *See, e.g., Texas Instruments, Inc. v. Cypress Semiconductor Corp.,* 90 F.3d 1558, 1567 (Fed. Cir. 1996) ("a patentee must . . .

provide particularized testimony and linking argument as to the 'insubstantiality of the differences' between the claimed invention and the accused device or process, or with respect to the 'function, way, result' test when such evidence is presented to support a finding of infringement under the doctrine of equivalents. Such evidence must be presented on a limitation-by-limitation basis."); *American CalCar v. American Honda*, 651 F.3d 1318, 1339 (Fed. Cir. 2011) ("Generalized testimony as to the overall similarity between the claims and the accused infringer's product from one of the inventors does not suffice to create a genuine issue of material fact."). As such, Enzo has waived any equivalents claim, and summary judgment of no infringement under the doctrine of equivalents is warranted.

3. Even if Enzo could raise a doctrine of equivalents argument at this late stage, the ULYSIS products do not and cannot infringe as a matter of law.

Any belated attempt to advance a doctrine of equivalents argument at this late stage must fail on the merits as a matter of law for at least three reasons: First, PHE absolutely bars application of the doctrine of equivalents to the ULYSIS products; second, the differences between the ULYSIS products and claim 1 are not "insubstantial"; and third, stretching the claim to cover ULYSIS would improperly ensnare the prior art.

i. Prosecution history estoppel absolutely bars infringement under the doctrine of equivalents.

PHE applies to and bars any claim of infringement under the doctrine of equivalents because Enzo represented to the PTO that claim 1 does not cover prior art that put labels on oligo- and poly-nucleotides (as do the ULYSIS products) as opposed to putting labels on free-standing mononucleotides. *See, e.g., American CalCar,* 651 F.3d at 1340 (argument that prior art was different than claimed invention "clearly and unmistakably surrendered subject matter that ACI now seeks to claim" for purposes of infringement under the doctrine of equivalents); *Festo VIII*, 535 U.S. at 737 ("patentee who narrows a claim as a condition for obtaining a patent disavows his claim to the broader subject matter"); *Warner-Jenkinson*, 520 U.S. at 33 (narrowing of claims creates presumption that change was made for reasons substantially related to patentability). To escape PHE, the patentee bears the burden of proving that an amendment was

not made for a reason that would give rise to estoppel and that the amendment does not surrender the particular equivalent in question. *Festo VIII*, 535 U.S. at 740-41. This Enzo cannot do.

None of the three narrow exceptions to PHE apply here: (1) that the alleged equivalent would have been unforeseeable at the time of the narrowing representation, (2) that the rationale underlying the representation bore no more than a tangential relation to the equivalent in question, or (3) that there was "some other reason" the patentee could not have been expected to describe the alleged equivalent. *See Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.*, 344 F.3d 1359, 1369 (Fed. Cir. 2003) (*en banc*) *(Festo IX*, ") (quoting *Festo VIII*, 535 U.S. at 740-41). Regarding foreseeability, Enzo's statements to the PTO in the reexamination were made to avoid prior art (the Draper reference) that Enzo characterizes as attaching labels to oligo- or polynucleotides – exactly the way the ULYSIS products function. **Exhibit 6** (Enzo's Response). The Draper reference was published in 1980, before even the earliest claimed priority date for the '060 patent and more than 30 years before Enzo made the narrowing representation. Enzo had also been asserting infringement against the alleged equivalent for more than 10 years before it made the narrowing representation to the PTO. Accordingly, Enzo cannot credibly assert that it was unaware of the alleged equivalent (*i.e.,* presumably the polynucleotide labeled using the ULYSIS product) or that it was "unforeseeable."

Likewise, Enzo cannot argue that its representations to the PTO bore only "a tangential relation to the equivalent in question," or that there was "some other reason" Enzo could not have been expected to include the alleged equivalent in the '060 patent. Indeed, Enzo's representations to the PTO bear directly and inescapably on the very distinction between the claims (as narrowed by Enzo) and the ULYSIS products that precludes literal infringement. Accordingly, Enzo is barred from relying on the doctrine of equivalents for infringement.

ii. The differences between claim 1 and the ULYSIS products cannot be considered "insubstantial."

Enzo, its experts, and the '060 patent itself all concede that a "nucleotide" is entirely different than an "oligonucleotide" or "polynucleotide," that the terms cannot be used interchangeably, and that oligo- and poly-nucleotides are not equivalents of the claimed

"nucleotide." *See* **Exhibits 3** ('060 at Col. 31, *ll* 14-17 (identifying "nucleotide" as molecule having phosphate moiety ("PM"), sugar moiety ("SM"), and base moiety ("BASE"), modified by a signaling moiety ("Sig") in contrast to claims 2 and 3, which relate to oligo- and polynucleotides "comprising at least one nucleotide in accordance with claim 1."), **4** (Sinden Decl. ¶¶23-24 (separately discussing nucleotides in one section, and oligo- and polynucleotides in another)), **7** (Rokita Decl. at ¶4) (the claims "echo this distinction by separately reciting oligo and polynucleotides in claims 2 and 3 as different from the 'nucleotide' of claim 1."); see also**9** (ULYSIS Product Information Sheet), and **5** (Sept. 11-12 2006 Singer Depo., Vol. 2, at 385:1-2 and 399:14-15) [redacted]

Moreover, Enzo confirmed the existence of *substantial* differences in the reexamination by relying on the distinction between the labeling of oligonucleotides and polynucleotides in the prior art (and in the ULYSIS products) and the labeling of a mononucleotide in claim 1 to overcome a rejection. *See* **Exhibit 6** (Enzo's Response at 6-7). Enzo has therefore ***by definition*** conceded that the differences are not insubstantial and must accept the consequences. *See, e.g., Regents of the Univ. of Minn.*, 2013 U.S. App. LEXIS 11077 at *30 ("When an applicant tells the PTO that a prior art reference lies outside the scope of his claim, he is bound by that argument"). Accordingly, even if PHE did not bar Enzo from relying on the doctrine of equivalents for infringement, a doctrine of equivalents theory must fail as a matter of law.

iii. Any doctrine of equivalents theory would improperly ensnare the prior art

Enzo distinguished the prior art on the basis that oligo- and polynucleotides are not the same as the claimed "nucleotide." To now assert that claim 1 can be "stretched" to cover labeling of oligo- and polynucleotides in addition to labeling of mononucleotides would result in the claim covering the prior art that Enzo distinguished in the reexamination. This is improper as a matter of law. *Wilson Sporting Goods Co. v. David Geoffrey & Assoc.,* 904 F.2d 677, 684 ,687 (Fed. Cir. 1990) ("as a matter of law, a range of equivalents broad enough to cover Dunlop's balls would also have encompassed the prior art"), *overruled in part on other grounds*, *Cardinal*

Chem. Co. v. Morton Int'l, Inc., 508 U.S. 83, 92 n.12 (1993).; *Depuy Spine v. Medtronic Sofamore Danek, Inc*., 567 F.3d 1314, 1325 (Fed. Cir. 2009) (ensnarement starts with a hypothetical claim that literally covers the accused device and "[i]f such claim would be unpatentable [over the prior art], then the patentee has overreached and the accused devices is noninfringing as a matter of law"). Accordingly, even if PHE did not bar Enzo from relying on the doctrine of equivalents for infringement, a doctrine of equivalents theory must fail as a matter of law because it ensnares the art.

IV. CONCLUSION

For the above reasons, MPI respectfully requests that the Court enter summary judgment in its favor with respect to Enzo's infringement claims against the ULYSIS products.

Respectfully submitted,

Dated: July 22, 2013

/s/Eric M. Jaegers

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CERTIFICATE OF SERVICE

The undersigned hereby certifies that all counsel of record who have appeared and are deemed to have consented to electronic service are being served with a copy of the foregoing document (and all accompanying documents) via the Court's CM/ECF system per Local Civil Rule 5.2 on July 22, 2013. Any other counsel of record will be served with a true and correct copy of the foregoing by first-class mail or E-mail.

/s/ Eric M. Jaegers
Eric M. Jaegers